DEC 14 2006

Section 5.0- 510(k) Summary
(Prepared in accordance with 21 CFR Part 807.92)

a. Submitted

Applicant Name:	ABIOMED, Inc.
	22 Cherry Hill Drive, Danvers, MA 01923
Contact Person:	Robert T.V. Kung, Ph.D.
Date Summary Prepared:	August 30, 2006

b. Device information

Trade Name:	SupraCor Balloon Catheter
Common Name:	Intra-Aortic Balloon Catheter and insertion kit
Classification Name:	Intra-aortic Balloon (classified under CFR870.3535)
Product Code:	74DSP

c. Legally Marketed Predicate Devices

Datascope Fidelity IAB catheter (K 980385), 8 F, 40 cc Intra-Aortic Balloon catheter

Arrow Ultra 8 IAB catheter (K000729), 8 F, 40 cc Intra-Aortic Balloon catheter

d. Device Description:

The SupraCor Balloon Catheter is a 40cc symmetrical polyurethane balloon attached to an 8 Fr dual lumen catheter, designed to provide counterpulsation cardiac assist therapy. The outer lumen is a channel for helium used to inflate and deflate the balloon, and the inner lumen is used for a guidewire and blood pressure measurement.
The balloon inflation and deflation cycle is synchronized (using a commercially available control console) with the ECG or arterial pressure to provide counterpulsation synchronized with the heartbeat. It is intended to increase coronary perfusion, decrease the workload of the left ventricle and allow healing of the myocardium.

e. Intended Use:

The SupraCor Balloon Catheter is placed in the descending aorta just below the subclavian artery and intended to improve cardiovascular functioning during the following situations:

- Unstable refractory angina
- Impending infarction
- Post Infarction Angina or Threatening Extension of Myocardial Infarction
- Refractory ventricular failure
- Mechanical complications because of myocardial infarction
- Cardiogenic shock

- Support and stabilization of high risk patients undergoing diagnostic and non-surgical procedures
- Ischemic related intractable ventricular arrhythmias
- Septic shock
- Interoperative pulsatile flow generation
- Weaning from cardiopulmonary bypass
- Cardiac support for high risk surgical patients and coronary angiography and angioplasty patients
- Prophylactic support in preparation for cardiac surgery
- Post-surgical myocardial dysfunction
- Cardiac Contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects
- Support for failed angioplasty and valvuloplasty

f. Technological Characteristics and Comparison to Predicate Device(s):

The SupraCor Balloon Catheter is of similar design and made of materials commonly used in other marketed balloon catheters. The insertion kit contains instruments commonly provided for insertion of an IAB.
Table 1 provides a comparison of the SupraCor Balloon Catheter with predicate balloon catheters, the Datascope 40cc Fidelity and Arrow 40cc Ultra 8. This table illustrates the equivalency of the SupraCor Balloon Catheter with the predicates.
Table 1- Comparison Table for SupraCor Balloon Catheter

Feature	**SupraCor IAB**	**Fidelity IAB**	**Ultra 8 IAB**
510(k) approval	This Submission	K980385	K000729
Duration of Use	Temporary use: Approx. ≤ 30 days	Temporary use: Approx. ≤ 30 days	Temporary use: Approx. ≤ 30 days
Balloon: Size Shape Material Length (in)	 40 cc Symmetric Polyether urethane 10.25	 40 cc Symmetric Polyether urethane 10.4	 40 cc Symmetric Polyether urethane 10.25
Catheter: Type Outer wall material Outer wall circumference	 Dual Lumen Polyether urethane 8 F	 Dual Lumen Polyether urethane 8 F	 Dual Lumen Polyether urethane 8 F
Introducer Size	8 F	8 F	8 F

Sterilization	EtO	EtO	EtO
Inner Packaging	Tray in Tyvek/Mylar Pouch	Tray in Tyvek/Mylar Pouch	Tray in Tyvek/Mylar Pouch
Outer Packaging	Tyvek Mylar Pouch	Tyvek Mylar Pouch	Tyvek Mylar Pouch

g. Pre-clinical Test Results:

Three different types of pre-clinical testing were completed for the SupraCor Balloon Catheter: laboratory, biocompatibility and sterility tests. The laboratory tests demonstrated equivalence to the 2 predicate devices, and included performance and reliability testing in accordance with FDA's recommendations, as provided in the Guidance for the Preparation and Contents of Applications to the Food and Drug Administration for Determining the Equivalence of Intra-Aortic Balloon Catheters and Consoles under the 510(k) Regulations (12/8/1993 draft). The biocompatibility and sterility testing showed that the SupraCor Balloon Catheter complies with the requirements for this device classification. The pre-clinical test results demonstrate that the SupraCor Balloon Catheter is safe and effective.

h. Conclusion:

Based on the information presented in this 510(k) premarket notification, the SupraCor Balloon Catheter is considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2006

Robert T.V. Kung, Ph.D.
Chief Scientific Officer
Abiomed, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Re: K062582
Abiomed SupraCor Balloon Catheter
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon and Control System
Regulatory Class: Class III
Product Code: DSP
Dated: November 28, 2006
Received: November 29, 2006

Dear Dr. Kung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062582

Device Name: SupraCor Balloon Catheter

Indications for Use:

The intra-aortic balloon is placed in the descending aorta just below the subclavian artery and intended to improve cardiovascular functioning during the following situations:

- Unstable refractory angina
- Impending infarction
- Post Infarction Angina or Threatening Extension of Myocardial Infarction
- Refractory ventricular failure
- Mechanical complications because of myocardial infarction
- Cardiogenic shock
- Support and stabilization of high risk patients undergoing diagnostic and non-surgical procedures
- Ischemic related intractable ventricular arrhythmias
- Septic shock
- Interoperative pulsatile flow generation
- Weaning from cardiopulmonary bypass
- Cardiac support for high risk surgical patients and coronary angiography and angioplasty patients
- Prophylactic support in preparation for cardiac surgery
- Post-surgical myocardial dysfunction
- Cardiac Contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects
- Support for failed angioplasty and valvuloplasty

Prescription Use X *AND/OR* *Over-The-Counter Use* _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of 2

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062582